Remarks

Applicants thank the Examiner for the indication of the allowablity of claims 6,

27, 34, 41, and 43.

Rejection of Claims 8, 15, and 21 Under 35 U.S.C. §112, first paragraph

Claims 8, 15, and 21 stand rejected under 35 U.S.C. §112, first paragraph as

allegedly lacking enablement. Applicants respectfully traverse the rejection.

Claim 15 recites a specific binding protein that specifically binds an isolated and

purified peptide comprising an amino acid sequence that consists essentially of Thr-Leu-

Leu-Glu-Tyr-Arg-Met (SEQ ID NO:4), or a variant thereof, wherein the variant

comprises an amino acid substitution at amino acid positions 3, 4, or both 3 and 4.

Claim 8 is dependant on claim 15 and recites that at least one amino acid substitution is

an amino acid with an aromatic ring.

Claim 21 recites a specific binding protein that specifically binds an isolated and

purified peptide comprising an amino acid sequence that consists essentially of Gly-Met-

Asn-Leu-Thr-Trp-Tyr-Arg-Glu-Ser-Lys (SEQ ID NO:5), or a variant thereof, wherein the

variant comprises an amino acid substitution at amino acid position number 5, 6, or both

5 and 6.

The Office Action asserts that Applicants have not demonstrated that the variant

peptides exist on IgE bound to B cells or on free IgE. The Office Action concludes that

antibodies that bind to unknown variant peptides would have no use. The Examiner

further asserts that the ability of an antibody resulting from immunization with a variant

peptide to bind the original peptide is unpredictable in view of Coleman et al. and

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Lederman et al. As such, the Office concludes that the resulting antibody would have no

use.

The claims are drawn to specific binding proteins, e.g., antibodies. The claimed

specific binding proteins are useful for, inter alia, diminishing the production of IgE in a

dog. See, e.g., page 32, lines 3-11. The claims specify that the specific binding proteins

specifically bind an isolated and purified peptide comprising an amino acid sequence that

consists essentially of SEQ ID NO:4, SEQ ID NO:5, or specified variants thereof. That

is, the claimed specific binding proteins bind SEQ ID NO:4, SEQ ID NO:5, or specific

variants thereof. The specification teaches that variant polypeptide character is not

substantially affected relative to the starting peptide (e.g., SEQ ID NO:4 or SEQ ID

NO:5). Variant polypeptide character is not substantially affected if the variations do not

preclude specific binding of the variant peptide to a specific binding protein of the

starting peptide. See specification, page 15, lines 10-17. That is, the claimed specific

binding proteins specifically bind to BOTH the starting polypeptide (e.g., SEQ ID NO:4)

AND the variant polypeptides.

Therefore, a claimed specific binding protein that specifically binds a variant

polypeptide will ALSO specifically bind to the starting polypeptide (e.g. SEQ ID NO:4

or SEQ ID NO:5). As such, the use of a specific binding protein that specifically binds

to a variant of SEQ ID NO:4 or SEQ ID NO:5 is the same as for specific binding proteins

that specifically bind to SEQ ID NO:4 or SEQ ID NO:5, that is, diminishing the

production of IgE in a dog. The existence of the variant sequences on IgE bound to B

cells is of no importance, the claimed specific binding proteins specifically bind to SEQ

ID NO:4, SEQ ID NO:5 AND the specified variant sequences.

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The Office also asserts that the claims stand rejected for reasons set forth in Paper

No. 22 (Office Action mailed 5/21/2001) and Paper No. 16 (Office Action mailed

10/24/2000). Under 35 U. S. C. § 112, all that is required is that the specification

describe the invention in such terms as to enable a person skilled in the art to make and

use the invention. Thus, the specification must teach one skilled in the art how to make

and use a specific binding protein that binds to an isolated and purified peptide

comprising an amino acid sequence that consists essentially of SEQ ID NO:4 SEQ ID

NO:5 or a variant thereof, wherein the variant comprises an amino acid substitution at

amino acid positions 3, 4, or both 3 and 4 for SEQ ID NO:4 and at amino acid positions

5, 6, or both 5 and 6 for SEQ ID NO:5.

The test of enablement is whether one reasonably skilled in the art (1) could make

and use the invention (2) from the disclosures in the patent coupled with information

known in the art (3) without undue experimentation. In re Wands, 858 F.2d 731 (Fed.

Cir. 1988); United States v. Telectronics, Inc., 857 F.2d 778 (Fed. Cir. 1988); M.P.E.P. §

2164.01. "The determination of what constitutes undue experimentation is a given case

requires the application of a standard of reasonableness, having due regard of the nature

of the invention and the state of the art." In re Wands, 8 U.S.P.Q.2d 1400, 1404 (Fed.

Cir. 1988) (citing Ansul Co. v. Uniroyal, Inc., 169 U.S.P.Q. 759, 762-63 (2d Cir. 1971).

"The test is not merely quantitative, since a considerable amount of experimentation is

permissible, if it merely routine, or if the specification in question provides a reasonable

amount of guidance with respect to the direction in which the experimentation should

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proceed." Id.

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The specification clearly teaches that positions 3 and 4 of SEQ ID NO:4 and positions 5

and 6 of SEQ ID NO:5 can be any amino acid. The specification clearly teaches that

substitutions can be made within a core sequence of SEQ ID NO:4 or SEQ ID NO:5.

Specifically, the specification teaches that a core peptide sequence comprises Leu-Xaa-

Xaa-Tyr-Arg (SEQ ID NO:1). See page 10, lines 16-23. Both SEQ ID NOs:4 and 5

comprise the core sequence of SEQ ID NO:1 and can therefore comprise substitutions

between the core Leu residue and the Tyr-Arg pair. Applicants remind the Office that the

Office must accept at being true the statements supporting enablement unless there is an

objective reason, usually supported with documentary evidence to question them.

The specification also provides routine assays that can be used to determine if a

claimed specific binding protein of the invention specifically binds a variant peptide. See

Example 2.

Therefore, one of skill in the art could make and use the a specific binding protein

that binds to a polypeptide shown in SEO ID NO:4, SEO ID NO:5, or the recited variants

of SEQ ID NO:4 and SEQ ID NO:5. As such the claimed variants are enabled by the

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specification. Applicants respectfully request withdrawal of the rejection.

Respectfully submitted,

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